REMARKS

Claims 1-28 are pending and stand rejected. In reply to the rejections in this Action, applicants have amended Claims 2, 3 and 31. Claim 33 has been canceled without prejudice or disclaimer to the subject matter claimed therein. Reconsideration is respectfully requested in view of the following remarks.

Applicants respectfully submit that the present amendments can be entered at this stage of prosecution. Specifically, the amendments reduce the total number of claims, reduce the number of issues remaining, and attend to matters of form. Moreover, the claim amendments require no further art searching on the part of the examiner.

Claim Rejections - 35 U.S.C. §112

Claims 2 and 31 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Action stated that the original specification fails to support the claimed "about" language.

In response, applicants respectfully submit that the amendments to claims 2, 3 and 31 render this rejection moot.

Claim Rejections - 35 U.S.C. §102/103

Claims 1, 2, 4-8, 12, and 16-28 and new claims 29-33 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,179,872 to Bell et al. (hereinafter referred to as "Bell"). Applicants respectfully traverse these rejections.

The claims were rejected for reasons already of record--namely, that Bell allegedly discloses centrifuged compositions in column 9, lines 17-67.

While Bell can use centrifuging as part of his technique to produce his fibrillar mats, the main embodiment seems to be simply pouring fibril-containing solution or gel over a screen or filter. Even in Example 3 where Bell does apply centrifugation of his fibrils, he mitigates or possibly eliminates its effect by re-dispersing the fibrils to make a slurry, and depositing them by pouring the slurry onto a screen.

However, even if Bell's centrifuging were the same as applicants', there is an even more fundamental reason why the claimed invention is patentably distinct from that of Bell.

The claimed invention is directed to biocompatible polymer <u>fibers</u>. In contrast, the Bell invention is directed to biopolymer <u>fibrils</u>. More specifically, the Bell invention is directed to "biopolymer scaffolds in the form of biopolymer matt or biopolymer matt composites..." (Column 1, lines 24-27). Further, "the term 'matt' refers to a biopolymer scaffold comprising a densely packed random array of biopolymer fibrils or bundles of fibrils or particles, e.g.,

collagen fibrils." (Column 7, lines 26-29) Bell recites a specific definition for the term "fibrils" as used in his disclosure and goes on to distinguish between collagen fibrils and fibers. (Column 7, lines 44-53)

Bell himself acknowledges that "multiple bundles of fibrils form fibers." So, Bell seems to be clear about the difference between fibers and fibrils, and he expressly claims the fibrils, not the fibers. But so what? What is the significance between a fiber and a fibril? Isn't a fibril just a miniature version of a fiber? The answer is "no", and that there are significant differences between the two other than relative size. In particular, the biopolymers listed by Bell are of a type that exhibit a hierarchy of structure, whereby fibrils are the smaller building blocks upon which fibers are constructed. In the case of collagen, bundles of fibrils organize and cross-link to form fibers, and it is at the fiber level of structural organization that the physical properties that differentiate the various collagen-containing tissues in a living being begin to express themselves. The attached Appendix A, consisting of several passages from the scientific literature, further expounds on these differences between collagen fibers and fibrils. One significant difference that has immediate applicability to the present invention is that, at least in the collagen system, a collagen fiber is stronger and has greater in-vivo persistence than a collagen fibril, two properties that can be important in biomedical applications. Further in support of these statements, applicants attach as Appendix B, a Declaration of Co-inventor Timothy A. Ringeisen.

Please note, though, that applicants have also disclosed collagen in fibril form. See, for example, the paragraph bridging pages 10 and 11 of the specification. Further, the claimed invention does not exclude fibrils. However, to applicants, it is the fiber form that is important, and they have claimed accordingly. Bell neither discloses nor suggests centrifuged fibers.

Accordingly, applicants respectfully request that these rejections be withdrawn.

Claim Rejections - 35 U.S.C. §103

Claims 3 and 13-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bell in combination with U.S. Patent No. 4,066,083 to Ries (hereinafter referred to as "Ries"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that neither Bell nor Ries, whether taken individually or in combination, discloses or suggests the claimed invention. As mentioned above, Bell neither discloses nor suggests the claimed fibers. Ries fails to remedy this deficiency of Bell.

Accordingly, applicants respectfully request that this rejection be withdrawn.

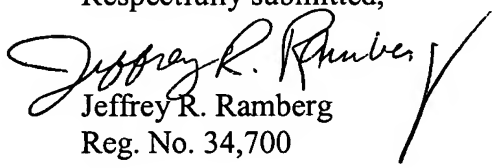
CONCLUSIONS

The claimed invention is neither anticipated nor rendered obvious by the cited references, applicants respectfully submit. The claimed invention utilizes fibers, whereas Bell uses fibrils, which he distinguishes from fibers. The candidate list of biopolymers from which Bell chooses exhibit a hierarchy of structure, in which fibers are made from smaller subunits called fibrils. Bell chooses to use the fibrils, not the fibers. In contrast, the claimed invention, while not excluding fibrils as an adjunct, is directed to, and therefore must always include, fibers, or their equivalent.

In view of the carefully amended claims and the above remarks, applicants respectfully submit that the present application is in condition for allowance. Accordingly, applicants respectfully request issuance of a Notice of Allowance directed to claims 1-32.

Should the Examiner deem that any further action on the part of applicant would be desirable, the Examiner is invited to telephone applicants' undersigned representative.

Respectfully submitted,



Jeffrey R. Ramberg
Reg. No. 34,700

February 28, 2005

c/o Kensey Nash Corporation
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Exton, PA 19341
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Enclosure: Appendix A: Supplemental citations and illustrations regarding the structure of collagen taken from the scientific literature

Appendix B: Declaration of Co-inventor Timothy A. Ringeisen

Appendix A

Supplemental citations and illustrations regarding the structure of collagen taken from the scientific literature

REFERENCES:

Title: Viscoelasticity of Biomaterials:
Chapter: 1. Hierarchical Structure of Collagen Composite Systems: Lessons in Biology
Pages : 2-23
Copyright: 1992 American Chemical Society, Washington, DC 1992

"All soft connective tissues have remarkably similar chemistry at the macromolecular [tropocologan] and fibrillar levels of structure. This similitude extends through the collagen fibril which is the basic building block of all soft connective tissues. Differentiation in the hierarchical structure takes place when these fibrils are arranged in a particular architecture, thus constructing a particular tissue for a unique function." "The upper levels of the hierarchical structure or architecture are organized with specific mechanical and transport requirements in mind."

"This [tropocollagen molecule] is a coiled coil of three helical polypeptides 290 nm in length. Five of these molecules align longitudinally with an overlap o f approximately one-quarter the molecular length to form a microfibril with a diameter of 3.6nm." "The microfibrils are then assembled into collagen fibrils that may vary in thickness from 35 to 500nm . These basic building blocks are combined, oriented, and laid up to form higher ordered structures with a particular morphology to suit the requirements of a tissue."

Histologically "one observes that in young animals, the fibrils are of small diameter and they are essentially the same size. As the animal matures and ages, the fibrils get larger and the range of the fibril sizes broadens considerably."

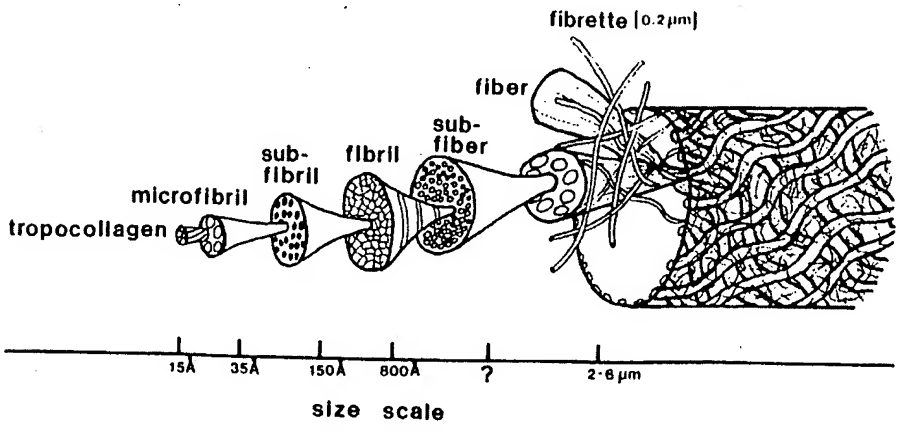


Figure 11. Hierarchical structure of the intestine. The hierarchical organization of the intestine is identical to that of the tendon from the molecular through the fibrillar level. The two tissues differ only in how the collagen fibrils are arranged into the highest levels of structure. Note that in the intestine no fascicles are present. Instead, the collagen fibrils aggregate into fibers which are then wound around the intestine in a helical fashion. (Reproduced with permission from reference 16. Copyright 1982 Gordon & Breach.)

Title:	An Introduction to Tissue-Based Interactions
Chapter 2:	Proteins
SubSection 2.7.1:	Collagen
Pages:	26-29
Copyright:	2002 by John Wiley & Sons Inc, Hoboken, NJ.

"After secretion from cells, the propeptides are enzmatically cleaved from the procollagen molecules to form collagen molecules, which are 1.5 nm in diameter and about 300 nm long. Collagen molecules undergo a self-assembly process to form collagen fibrils 10 – 300 nm in diameter. Assembly results in a quarter-stager array of collagen molecules, in which overlapping rows of molecules are staggered by about one-quarter of the length on an individual molecule. This arrangement gives collagen fibrils characteristic striations every 67 nm when viewed by transmission electron microscopy. Fibrils can aggregate to form collagen fibers, which can be several micrometers in diameter."

Title:	Atlas of Descriptive Histology / Third Edition
Chapter 2:	Connective Tissue
Plate 2.2:	Connective Tissue, Electron Microscopy
Plate 2.3	Connective Tissue Cells, Electron Microscopy
Pages:	22-25
Copyright:	1977 by Edward J. Reith and Micheal H. Ross Harper & Row, Publishers, New York.

"In all three figures, the collagen fibrils can be clearly identified as the subunits of the collagen fibers (CF)" " Again, it is indicated that individual fibrils cannot be identified with the light microscope, rather, one sees a bundle of fibrils and this bundle is then referred to as a collagen fiber. One can also ascertain from these illustrations that the diameter of the collagen fiber depends on how many fibrils are within the bundle."

Title: Hams Histology – Ninth Edition
Chapter 7: Loose Connective Tissue and Adipose Tissue
Section: Connective Tissue Fibers
Pages: 156-161
Copyright: 1987 by J.B. Lippincott Company, Philadelphia

"Collagen fibers are characteristically thick and unbranched, with a diameter of 2 micrometers 10 micrometers, and in spreads they commonly appear wavy. Careful focusing under the microscope discloses that they are made up of smaller collagen fibrils."

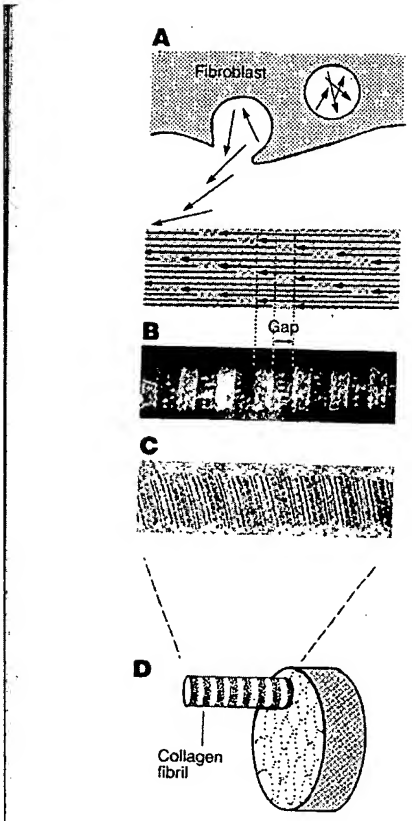
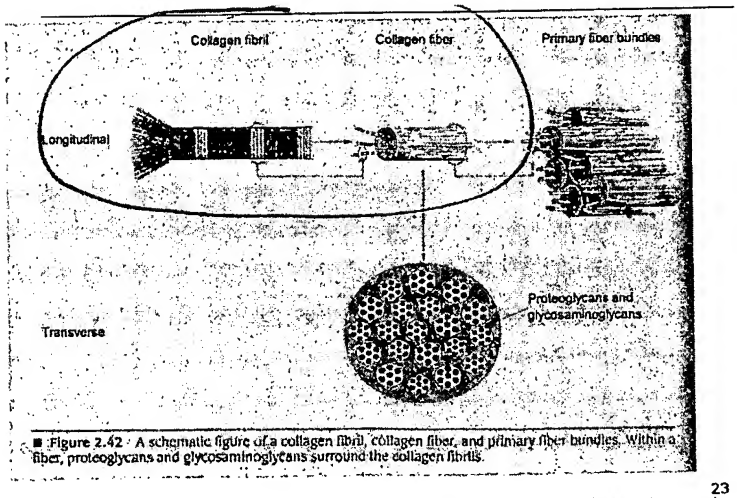


Fig. 7-5. Diagram summarizing the formation and periodicity of collagen fibrils. Collagen molecules (*arrows*) from fibroblasts undergo extracellular assembly (*A*), becoming incorporated into the component fibrils of collagen fibers (*D*). The electron micrographs illustrate collagen fibrils after (*B*) negative staining and (*C*) conventional staining. See text for details. (*B*, courtesy of A. Howatson and J. Almeida; *C*, courtesy of H. Warshawsky)

to



■ Figure 2.42 · A schematic figure of a collagen fibril, collagen fiber, and primary fiber bundles. Within a fiber, proteoglycans and glycosaminoglycans surround the collagen fibrils.

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(From "Human Tendons" by Józsa and Kannus)

Appendix B

DECLARATION OF INVENTOR TIMOTHY A. RINGEISEN

I, Timothy A. Ringeisen, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/601,206, entitled "High Density Fibrous Polymers Suitable for Implant";

That I am named as an inventor or co-inventor on 3 issued U.S. Patents and 10 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Biology from Gustavus Adolphus College, and a Master of Industrial Hygiene from University of Minnesota;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as a Senior Scientist;

That I have 5 years experience in this position, and that I have 16 years experience overall as a Biomaterials Engineer;

That I am familiar with the invention claimed in the above-identified patent application;

That the claimed invention relates to a fibrous composition that is suitable for implant in a living being, and which is useful in the repair and/or reconstruction of tissue, for example, to facilitate or promote growth of new tissue;

Specifically, that when a slurry containing biocompatible polymer fibers is centrifuged, the fibers migrate to the far end of the vessel, and begin to interact with one another to produce desirable mechanical/physical properties;

For example, that such centrifuged fibers can be rehydrated to a dough consistency, and this viscous product can be self-supporting and will resist dissociation of fibers in service, for example, during exposure to body fluids;

That I am familiar with biocompatible polymers, or "biopolymers" that can exist in fiber form;

That I am furthermore familiar with certain biopolymers such as collagen that exhibit a hierarchy to their structure;

That I am familiar with collagen chemistry;

That collagen is a chain-like protein commonly found in connective tissue in a living organism;

That a collagen molecule can be considered to be the three strands of polypeptide material that hydrogen bond to one another in a triple helix arrangement called "tropocollagen";

That as the polymerization reaction continues, multiple numbers of these triple helix formations self-assemble together to form a **fibril** of collagen;

That a multiple of collagen fibrils associate into bundles;

That multiple bundles of collagen fibrils can associate, and that higher multiples of fibril bundles having a diameter in the range of 1-50 microns are classified as collagen **fibers**;

That I have reviewed all of the documents cited as prior art in the Office Action dated December 28, 2004;

That, in particular, I have thoroughly read and analyzed the disclosure in the cited U.S. Patent No. 6,179,872 to Bell et al.;

That Bell's reference to "fibrils", particularly "collagen fibrils" means collagen in the form of individual collagen fibrils, or bundles of such fibrils, and not in the form of collagen fibers;

That while the claimed invention does not exclude fibrils as, for example, an addition or adjunct, the claimed invention always requires the fiber form or its equivalent;

That, at least in the case of collagen, fibers of the claimed invention possess certain advantages over fibrils;

That, among other advantages, collagen fibers exhibit greater mechanical strength and greater in-vivo persistence than do collagen fibrils; and

That I understand that all statements made herein (including statements made in the attachment documents) of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Timothy A. Ringeisen

Timothy A. Ringeisen

28 Feb 05

Date